PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q117058

Bruno COVELLI

Appln. No.: 10/523,618

Group Art Unit: 3774

Confirmation No.: 1368

Examiner: STROUD, JONATHAN R

Filed: April 25, 2006

For: IN-VITRO METHOD FOR THE PRODUCTION OF A HOMOLOGOUS STENTED

TISSUE-ENGINEERED HEART VALVE

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the interview conducted on September 29, 2010:

REMARKS

This statement responds to the Examiner's Interview Summary Record (PTO-413) that was mailed to the Applicant on October 5, 2010.

During the interview, the following was discussed with respect to claim 1.

- 1. Brief description of exhibits or demonstration: None
- 2. Identification of claims discussed: Claim 1
- Identification of art discussed: Hoerstrup DE 19919625; Arru U.S. Patent No. 4,758,151.
- 4. Identification of principal proposed amendments: None
- 5. Brief Identification of principal arguments:

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(1) The Examiner indicated he would consider withdrawing the new matter rejection based upon the Applicant's explanation that the language "slowly degradable" can be found in claim 26 of the corresponding PCT/EP2002/009906 application which is incorporated by reference into the present application.

- (2) The Examiner stated that there is no evidence presently on the record that distinguishes the present invention from Hoerstrup and Arru. The Examiner contends that the teachings of the present application are merely attempting to claim a variation that is implicitly disclosed in Hoerstrup and Arru which would have been obvious to a person of ordinary skill at the time of the invention.
- (3) Applicant respectfully disagreed with the Examiner. Applicant argued:
- (a) that the matrix/ support of the present invention is distinct from the frame/stent taught in Arru, and
- (b) that Arru's stent is required continuously in order to provide rigidity to the heart valve, whereas the present invention requires conditioning of the heart valve to pulsatile flow in a bioreactor and then additional conditioning *in vivo* while attached to a frame. Applicant asserted this end result is different and not predictable based upon the teachings of Hoerstrup and Arru. Specifically, Arru's heart valve requires continuous support with a non-biodegradable stent whereas, after a year or so of conditioning *in vivo*, the frame of the present invention can degrade and the heart valve remains stable *in vivo*.
- 6. Indication of other pertinent matters discussed: None

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7. Results of Interview: The Examiner agreed to reconsider the 35 U.S.C §112

rejection in view of Applicant's assertion that the term "slowly degradable" can be found

in claim 26 of the corresponding PCT/EP2002/009906 which is incorporated by reference

to the present application. The Examiner conceded that the Arru reference does not teach

a frame that is biodegradable as required by Applicant's claimed invention.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF

INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

It is believed that no petition or fee is required. However, if the USPTO deems

otherwise, Applicant hereby petitions for any extension of time which may be required to

maintain the pendency of this case, and any required fee, except for the Issue Fee and the

Publication Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,

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Date: November 9, 2010

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